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APR - 5 1995

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Re: Fragmin

FDA Docket No. 95E-0055

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Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,303,651 issued December 1, 1981. The application was filed on February 15, 1995, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. 156(d)(2)(A).

Gerald A. Dost
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

cc: Burton A. Amernick
Pollock, Vande Sande & Priddy
1990 M Street, N.W.
P.O. Box 19088
Washington, D.C. 20036